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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,431	03/28/2002	Kakuji Tojo	13357.4USWO	6928

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,431	Applicant(s) TOJO ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement of Papers Received: Preliminary Amendment filed 03/28/02 and Information Disclosure Statement 06/24/02.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hille et al (USPN 5,700,480). The claims are drawn to an ophthalmic transdermal patch comprising a matrix with a percutaneous absorption enhancer, and a drug. The claims recite that the matrix comprises either acrylic or silicone based adhesive polymers. The penetration enhancers are selected from polyoxyethylene oleyl or isopropyl myristate.

Hille et al teaches an ophthalmic transdermal system. The transdermal patch comprises a glaucoma drug, an acrylic based matrix that further comprises penetration enhancers including isopropyl myristate (col. 1, lin. 40 – 49; col. 2, lin. 23 – 50; examples). These disclosures render the claimed invention anticipated.

3. Claims 1 – 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al (USPN 5,656,286).

Miranda et al teaches transdermal patch which can deliver ophthalmic drugs, including anti-inflammatory agents among many others. The transdermal patch of Miranda comprises an acrylic based drug layer containing penetration enhancers such as isopropyl myristate (col. 10,

lin. 46 – 57; col. 11, lin. 13 – 19; col. 12, lin. 51 – col. 32, lin. 434; col. 33, lin. 17 – 21). These disclosures render the claimed invention anticipated.

4. Claims 1-3, 6, 11-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Deurer et al (USPN 5,869,086). Claims 1-3, and 6 are drawn to an ophthalmic transdermal patch comprising a drug and penetration enhancers. Claims 11-13, and 16 are drawn to a method of treating a disease of the eye using the patch of the invention.

Deurer et al discloses a transdermal patch for the treatment of glaucoma. The patch comprises an active agent that can treat the disease of the eye. The patch comprises an acrylic polymer based matrix, which further comprises penetration enhancers such as isopropyl myristate an oleyl alcohol. The patch was administers to patients for the treatment of the disease (col. 3, lin. 38 – 60; col. 4, lin. 22 – 25; examples). These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4 – 5, 7 – 10, 14 – 15, 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deurer et al (USPN 5,869,086) in view of Fukiage et al (EP 0 771 565). Claims 4 – 5, and 7 recite specific concentration of the transdermal components. Claims 11 – 20 recite a method for the treatment of a disease of the eye. The treatment comprises applying the transdermal patch of claims 1 – 10. Claims 14 – 15 and 17 recite specific concentrations of the transdermal components.

As discussed above Deurer discloses essential elements of the claimed inventions, specifically the penetration enhancers, drug-containing matrix composition and drug types. Deurer also discloses a method of treating an eye disease using a transdermal patch.

What is lacking in the references is a teaching of the N-(4-fluorophenylsulfonyl)-L-valyl-L-leucinal drug recited in claims 9, 10, 19 and 20. This ophthalmic drug and its salts are well known in the art and have been disclosed by Fukiage et al. Fukiage discloses that the drug can be useful in treating disorders eye, specifically the retina, and also discloses that transdermal delivery is possible (Abstract; pg. 2, lin. 49 – 52; formula (VI), pg. 4; pg. 13, lin. 45 – 50; pg. 38, lin. 2 – 11).

With regard to the claims 4, 5, 7, 14, 15, and 17, which recite specific ranges and concentrations of the penetration enhancers and polymer ratios, it is the position of the examiner that such recitations are non-critical to the patentability of the invention. Applicant is reminded that it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind, it would have been obvious to one of ordinary skill in the art to combine the teachings and suggestions of the art in order to treat diseases of the eye transdermally. A skilled artisan would have been motivated to substitute the active agent of Fukiage into the transdermal patch of Deurer in order to treat disorders of the eye, along with possibly Alzheimer's symptoms. It would have been obvious to combine these teachings and optimize their concentrations with an expected result of an ophthalmic transdermal patch that was useful in treating diseases of the eye.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

M. Young
March 3, 2003

GS Kishore

Gollamudi S. Kishore, Phd
Primary Examiner
Group 1600